§ 103 Rejections

Claims 11-20 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,750,136 ("Scholz") in view of U.S. Patent No. 5,527,610 ("Urry"). Of the rejected claims, only claim 11 is independent.

The Office Action states that Scholz discloses a bioadhesive composition that adheres suitably to a mucosal surface and is capable of delivering drugs in sustained fashion. The bioadhesive composition of Scholz comprises (1) a particulate polymeric resin, (2) a hydrophobic elastomeric component, and (3) a drug. The Office Action acknowledges that Scholz does not disclose the elastomeric polymer to be crosslinked.

Urry is said to disclose a bioelastomer comprising tetrapeptide and/or pentapeptide monomeric units. The bioelastomer can be crosslinked or uncrosslinked, and increased amounts of cross-linking are appropriate for increasing demands of rigidity.

The Office Actions argues that it would have been obvious to one of ordinary skill in the art to modify the elastomeric polymer taught by Scholz by crosslinking the polymer to provide strength and rigidity as taught by Urry. Applicants respectfully traverse the rejection.

The rejection of claims 11-20 under 35 U.S.C. § 103(a) fails to set forth a *prima facie* case of obviousness. M.P.E.P. § 706.02(j) states that in order to establish a *prima facie* case of obviousness, three basic criteria must be met:

(1) there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art to modify the reference or to combine reference teachings;

(2) there must be a reasonable expectation of success;

(3) the prior art reference(s) must teach or suggest all of the claim limitations.

Moreover, the teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on Applicants' disclosure.

First, the prior art references fail to teach or suggest all of the claim limitations. Specifically, neither Scholz nor Urry teach or suggest a transmucosal drug delivery device including an elastomeric polymer that is 30%-80% crosslinked.

Second, one of ordinary skill in the art at the time the invention was made would have had no motivation, either from the cited references or in the knowledge generally attributable to

one of ordinary skill in the art, to modify Scholz according to the teaching of Urry. Urry teaches that cross-linking provides mechanical strength and rigidity to the polymer, and increasing amounts of cross-linking are appropriate for increasing demands of rigidity (column 5, lines 65-67). However, Scholz does not identify rigidity demands as a concern or limitation of the bioadhesive compositions described therein. Thus, it is unclear why one of ordinary skill in the art would have been motivated to combine the teachings of Scholz and Urry as suggested in the Office Action.

Furthermore, the combined teachings of Scholz and Urry teach away from the transmucosal drug delivery patch recited in claim 11. Scholz teaches that the elastomeric components preferably are *soft* such that the ultimate composition can be worn without significant discomfort to the user (column 4, lines 42-44). Reading Scholz and Urry together, one of ordinary skill in the art would have been motivated to provide a low degree of crosslinking in the elastomeric polymer - not as much as 80% crosslinking - in order to manufacture a soft, comfortable transmucosal drug delivery device. Thus, the teaching of Urry - that a higher degree of crosslinking in the elastomeric polymer provides a higher degree of rigidity - would have directed one of ordinary skill in the art away from using an elastomeric polymer that is 30%-80% crosslinked, as recited in claim 11, for a soft, comfortable transmucosal patch including the bioadhesive composition of Scholz. In the absence Applicants' disclosure, there is no teaching or suggestion to include an elastomeric polymer that is 30%-80% crosslinked in the manufacture of a transmucosal drug delivery device.

The rejection of claim 11 under 35 U.S.C. § 103(a) as being unpatentable over Scholz in view of Urry has been overcome and should be withdrawn.

Each of claims 12-20 depends from claim 11. Thus, claims 12-20 are patentable for at least all of the reasons set forth above regarding the patentability of claim 11.

In summary, the rejection of claims 11-20 under 35 U.S.C. § 103(a) as being unpatentable over Scholz in view of Urry has been overcome. Withdrawal of the rejection is respectfully requested.

Conclusion

The remarks provided above are fully responsive to the Office Action mailed November 29, 2002. Applicants submit that the application is in condition for allowance. Reconsideration of the application is requested.

Allowance of claims 11-20 at an early date is solicited.

Respectfully submitted,

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veterinarian (or other skilled animal care provider), or prolonged hospitalization, cost prohibitive to the owner. In addition, the fractious nature of some animals can preclude safe drug administration to the animal even by skilled handlers. Moreover, in rural areas, emergency situations frequently necessitate therapeutic action sooner than a veterinarian can arrive to provide the necessary treatment. Because of these and other factors unique to providing health care to animals, physiological similarity is only one factor affecting the therapeutic benefit of a pharmacological agent across species lines.

Typically, drugs are administered to animals orally or parenterally. And, while some pharmacological agents are available in an oral dosage form, to ensure that the necessary dose is administered, many agents must be administered by injection or directly to the stomach using a stomach tube. These administration methods can ensure proper dose administration, however, repeated administration via injection or stomach tube can quickly become irritating and stressful to the animal as well as dangerous to the animal owner or health care provider.

GB-A-981 372 describes a solid formulation suitable for oral administration to animals, being in the form of wafers readily adherent to the tongue or buccal mucosa and comprising a physiologically active substance, a solid non-toxic adhesive, a non-toxic humectant and a plasticizer.

EP-A-0 654 261 relates to a solid mucoadhesive therapeutic or hygienic composition, for human or veterinary use, intended to be administered by application to the buccal or nasal mucous membrane, this composition comprising, in mixture, a cellulosic ether gelifiable in the presence of an aqueous liquid, a homopolymer or copolymer of acrylic acid or a physiological acceptable salt of that homopolymer or copolymer, and at least one therapeutic or hygienic active constituent.

WO-A-94/18925 describes a system for mucosally administering a macromolecular drug to the oral cavity comprising an inner drug/enhancer/polymer layer having one surface adapted to contact the mucosal tissue of the oral cavity and adhere thereto when wet and an opposing surface in contact with and adhering to an overlaying inert layer, said inert layer containing from about 2 to 60 wt.-% of a bile salt enhancer, 5 to 65 wt.-% of a hydrophilic polymer and an effective amount of a macromolecular drug having a molecular weight of at least 500 daltons.

Hence, there is a need for effective diagnostic and therapeutic products and methods for animals that are humane, cost effective, easy to administer, and safe for both the animal and the health care provider.

Summary of the Invention

The present disclosure is directed to new products and methods for safe, simple, effective, and humane treatment or diagnosis of a condition in animals. It will be appreciated, however, that many of the procedures disclosed herein can also be used advantageously for some human patients or conditions.

In several places throughout the specification, guidance is provided through lists of examples. In each instance, the recited list serves only as a representative group. It is not meant, however, that the list is exclusive.

The present invention provides safe and convenient drug delivery for short term or prolonged drug administration to a patient. The invention includes use of mucosal originated drug delivery systems. Included within mucosal originated drug delivery systems of the invention are known transmucosal drug delivery (TMDD) systems as well as new TMDD compositions. Mucosal originated drug delivery systems also include